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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/905,041	07/13/2001	Marc Madou	22727/04096	2217
24024	7590	10/09/2003	EXAMINER	
CALFEE HALTER & GRISWOLD, LLP			CHUNDURU, SURYAPRABHA	
800 SUPERIOR AVENUE			ART UNIT	PAPER NUMBER
SUITE 1400			1637	
CLEVELAND, OH 44114			DATE MAILED: 10/09/2003	
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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/905,041	MADOU ET AL.
	Examiner Suryaprabha Chunduru	Art Unit 1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.

- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 23 May 2003.

2a) This action is FINAL.                  2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-10, 12-15, 38-47 and 50-57 is/are pending in the application.

4a) Of the above claim(s) 15 and 38-40 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-10, 12-14, 41-47 and 50-57 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

**DETAILED ACTION**

1. Applicants' response to the office action (Paper No. 10) filed on May 23, 2003 has been entered and considered.
2. The Declaration submitted under 37 CFR 1.132 has been entered and considered.
2. Claims 1-2, 6-14 and 41 were considered for examination in the previous office action as these claims depend on elected species (proteins and polypeptides) are pending. Claims 3-5, 15, and 38-40 were withdrawn from further consideration. Claims 11, 16-37, 48-49 were canceled. New claims 52-57 are added.
3. Request for reconsideration of claims 1-2, 6-10, 12-14, 41-47, and 50-57, is acknowledged. Claims 1-2, 6-7, 9-10, 12-14, 41-47, 50-57 are considered for examination in this office action with respect to the elected species (proteins and polypeptides).

**Response to Arguments**

4. With reference to the rejection made in the previous office action under 35 USC 102(b), Applicant's amendment and arguments have been fully considered and the rejection is moot in view of the amendment and new grounds of rejection.
5. With reference to the rejection made in the previous office action under 35 USC 103(a), Applicant's amendment and arguments have been fully considered and the rejection is moot in view of the amendment and new grounds of rejection.

**New Grounds of Rejections**

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 1-2, 6-10, 12-14, 42-47, 52, and 56-57 are rejected under 35 U.S.C. 102(b) as being anticipated by Schultz (USPN. 5,162,218).

With reference to the instant claims 1-2, 8, 12, 14, 52, Schultz teaches a synthetic multimeric biopolymer comprising a plurality of monomeric units (amino acids), wherein, (i) monomeric units are covalently linked to each other and multimeric biopolymer (polypeptide) comprise a binding site for a ligand selected from peptide (antibody, biotin) (see column 5, lines 11-43, column 7, lines 44-62) (iii) wherein said monomeric units (amino acids) exhibit a detectable conformational change in response to binding of the ligand to said binding region (see column 6, lines 32-48) and the conformational change (three-dimensional structure) being detectable (by NMR) (see column 19, lines 1-4) by detecting a change in a reporter fluorophore that has been attached to said monomeric units (see column 6, lines 32-64); (iv) wherein monomeric unit comprising a fluorophore transmits a detectable signal which includes a fluorescent signal, or optical signal in response to a change in the conformation of the biopolymer (see column 9, lines 32-36, column 10, lines 28-50, column 17, lines 34-47).

With reference to the claims 6-7, Schultz teaches that (a) the biopolymer comprise proteins, enzymes, hormones etc. (see column 5, lines 31-38);

With reference to the instant claims 9-10 Schultz teaches that the biopolymer comprises a plurality of polypeptides (see column 5, lines 26-27) and said biopolymer comprises fewer than 200 monomeric units (see column 13, lines 24-27);

With reference to the instant claims 42-47, Schultz teaches that said synthetic biopolymer comprising monomeric units attached to each other by peptide bonds (sulfide bonds) or chemically crosslinked to each other by peptide bonds (see column 7, lines 42-62);

With reference to claim 50, Schultz teaches that the change in conformation of said biopolymer is reversible (see column 25, lines 16-64);

With reference to the claims 8, 13, 56-57, Shultz teaches that the biopolymer comprising polypeptides having a hydroxide, a cation other than a hydrogen ion, including oxyanion (see column 17, lines 11-33). Thus the disclosure of Schultz meets the limitations in the instant claims.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 41, 51, and 53-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schultz (USPN. 5,162,218) and in view of Nowinski et al. (4,711,840).

Schultz teaches (with reference to the claims 8, and 41) a synthetic multimeric biopolymer comprising a plurality of monomeric units (amino acids), wherein, (i) monomeric units are covalently linked to each other and multimeric biopolymer (polypeptide) comprise a binding site for a ligand selected from peptide (antibody, biotin) (see column 5, lines 11-43, column 7, lines 44-62) (iii) wherein said monomeric units (amino acids) exhibit a detectable conformational change in response to binding of the ligand to said binding region (see column 6, lines 32-48) and the conformational change (three-dimensional structure) being detectable (by NMR) (see column 19, lines 1-4) by detecting a change in a reporter fluorophore that has been attached to said monomeric units (see column 6, lines 32-64); (iv) wherein monomeric unit comprising a fluorophore transmits a detectable signal which includes a fluorescent signal, or optical signal in response to a change in the conformation of the biopolymer (see column 9, lines 32-36, column 10, lines 28-50, column 17, lines 34-47). Schultz teaches that (a) the biopolymer comprise proteins, enzymes, hormones etc. (see column 5, lines 31-38); the biopolymer comprises a plurality of polypeptides (see column 5, lines 26-27) and said biopolymer comprises fewer than 200 monomeric units (see column 13, lines 24-27); synthetic biopolymer comprising monomeric units attached to each other by peptide bonds (sulfide bonds) or chemically crosslinked to each other by peptide bonds (see column 7, lines 42-62); Schultz teaches that the change in conformation of said biopolymer is reversible (see column 25, lines 16-64); the biopolymer comprising polypeptides having a cation other than a hydrogen ion , including oxyanion (see column 17, lines 11-33). However, Schultz did not teach greater change in

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conformation as a result of an analyte binding to the biopolymer than that occurs in an individual monomeric unit as a result of binding to an analyte.

Nowinski et al. teach analyte-specific incorporation of fluorescence into a polymer, wherein Nowinski et al. teach a greater change in conformation, that is, a 20-fold increase in fluorescence as result of analyte binding to the biopolymer as compared to a control (see 15, lines 5-22). Nowinski et al. also teach reactant functional groups that bind to a biopolymer, which includes hydroxyl, amine, carboxy groups (see column 7, lines 17-67).

Therefore, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time to combine the multimeric polypeptides as taught by Schultz with the teachings of Nowinski et al. to achieve expected advantage of developing a multimeric bioplyomer having a greater efficiency in binding to an analyte because Nowinski et al. suggests that "polymers are of limited value in that the spacing and steric accessibility, and number of polypeptides bound per unit length of polymer cannot be precisely or reproducibly controlled and there is a need in the art to specifically tailor or molecularly engineer polymer compounds incorporating controlled quantities of reactants (see column 3, lines 3-22). An ordinary practitioner would have been motivated to combine the multimeric biopolymer of Schultz with the limitations as taught by Nowinski et al. to improve the configuration of the synthetic multimeric biopolymer structure by including the greater change in conformation as taught by Nowinski et al.

### ***Conclusion***

No claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and - for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding  
should be directed to the receptionist whose telephone number is 703-308-0196.

Suryaprabha Chunduru  
October 2, 2003

  
JEFFREY FREDMAN  
PRIMARY EXAMINER